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WHITE PAPER

Off-label unsolicited requests – How to respond ?

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Due to the rapid growth of the internet and social media tools, it is easier for both consumers and healthcare professionals to quickly seek information about medical conditions and treatments. As a result, firms may encounter requests for the off-label information about their products through product websites, discussion boards, chat rooms, forums that they maintain and have full control.

Statements that promote a drug or medical device for uses other than those approved or cleared by the FDA may be used as evidence of a new intended use. Introducing a product into the commerce for such a new intended use without FDA approval or clearance would generally violate the law.

This document provides the FDA recommendations to firms wishing to respond to unsolicited request for off- label information, including both requests made directly and privately to firms and request made in public forums and other electronic media.

Overview of FDA's policy

FDA has long taken the position that firms can respond to unsolicited requests for information about the FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional medical information that is responsive to the specific request. This document sets forth FDA's current thinking about responding to unsolicited requests. Information to be distributed in response to an unsolicited request should be scientific in nature.

Firms may choose to respond to unsolicited requests for information about off-label uses of their approved products in a manner other than that recommended and such activity would not constitute a per se violation of the law, but could be potentially introduced as evidence of a new intended use.

FDA recognizes that firms are capable of responding to requests about their own products in a truthful, non misleading information and accurate manner. The FDA recognizes that it can be in the best interest of the public health for a firm to respond to unsolicited requests for information about off-label uses of the firms products that are addressed to a public forum since they have the most accurate and up to date information.

Determining whether a request is Unsolicited or Solicited

Unsolicited Requests

Unsolicited request are those initiated by persons or entities that are completely independent of the relevant firm. Requests that are prompted in any way by a manufacturer or its representatives are not unsolicited requests.

Non-public Unsolicited Requests: An unsolicited request that is directed privately to a firm using one-on-one communication approach.

Example: An individual calls or emails the medical information staff at a firm seeing information about an off-label use. In such a case, neither the request not the response would be visible to the public.

Public Unsolicited Requests: A public unsolicited request made in the public forum, whether directed to a firm specifically or to a form a large.

Examples:

1. During a live presentation, an individual asks a question, directed to firm's representative but heard by other attendees, regarding off-label use of a specific product. This is a public request.
2. An individual post a question about off-label use of a specific product on a controlled website visible to a broad audience. The request could be directed to a firm specifically or posed to users of a discussion forum at large. This request is a public online request and the response by the firm would be a public online response.

Solicited Requests

FDA considers request for off-label information that are prompted in any way by a manufacturer or its representatives to be solicited. Such solicited requests may be considered as an evidence of a firm's intent that the drug or medical device be used for a use other than that specifically approved or cleared.

Examples that illustrate what FDA generally considers to be solicited requests for off-label information:

1. If a firm's sales representative mentions the use of the product that is not reflected in the products approved labeling and invites a health care professional to request for more information, the resulting request would be considered as solicited requests.
2. If the medical science liaison or paid speaker or key opinion leader of the representative firm, presents off-label use data at a company sponsored promotional event, then such requests would be considered as solicited requests.
3. If a firm provides a phone number, email address, uniform resource locator (URL), implying the availability of off-label information of its products, the requests using this phone number, email address, URL, would be considered as solicited requests.
4. If a firm sends out information to known bloggers or online consumer reviewers and encourages them to write about an off-label use of its product on third party sites, and this then provokes a discussion about the off-label use, any requests inquiring about the products off-label use as a result of the blogs, would be considered as solicited requests.
5. If the firm announces the results of the study via a micro blogging services such as Twitter, suggesting that the off-label use of its product is safe and effective, the comments and request received as a result of that message would be considered as solicited requests.

Responding to the non-public Unsolicited Requests for off-label information

FDA makes the following recommendations to a firm that is responding to a non-public unsolicited request for off-label information about its product that was specifically directed to a firm privately through a one-on-one communication.

1. Information distributed in response to an unsolicited request should be tailored to answer only the specific questions asked.

   A firm should ensure that all pertinent background data are obtained to be able to determine what information is being requested before providing a request. The level of specificity posed is important to ensure that the firm, response is tailored to the request.

   Example: An individual requests information on the use of a drug or device for one particular disease or condition that is considered off-label for that drug or device. Generally, a firm should provide information pertinent only to that disease or condition.

   However, if there is information about known or suspected risks associated with other diseases or conditions that is also relevant to the disease or condition for which information was requested, the firm should provide such information to ensure a complete and accurate presentation of the risk issues associated with the requested use.

2. Information distributed in response to an unsolicited request should be truthful, non-misleading, accurate and balanced. A response should provide non-biased or data relating to the particular off-label use that is the subject of the request, including applicable data that are not supportive or that cast doubt on the safety or efficacy of that use.

3. Information distributed in response to an unsolicited request should be scientific in nature.

   When responding to an unsolicited requested for information, affirm should respond with material that is scientific in tone and presentation. The material should not be promotional in tone or presentation.

4. Response to unsolicited requests for information should be generated by medical or scientific personal independent from sales or marketing departments.

   FDA recommends that questions or requests about off-label uses be referred to the firm's medical representative or department including appropriately narrowing questions, tailoring questions only to the specific questions being asked, providing unbiased responses, and properly documented responses.

5. Information distributed in response to an unsolicited request should be accompanied by the following:

   - A copy of the FDA-required labeling, if any for the product such as FDA approved package insert or patient labeling
   - A prominent statement notifying the recipient that FDA has not approved or cleared the product as safe and effective for the use of the addressed in the materials provided
   - A prominent statement disclosing the indications for which the FDA has approved or cleared the product
   - A complete list of references for all the information disseminated in the response

6. A firm should maintain the following records:

   - The nature of the request of the information, including the name, address and affiliation of the requestor
   - Records regarding the information provided to the requestor
   - Any follow-up inquiries or questions from the requestor

If a firm responds to non-public unsolicited requests for off-label information in the manner described above, FDA does not intend to use such references as evidence of the firm's intent that its product be used for an unapproved use. Such responses also would not be expected to comply with the disclosure requirements related to the promotional labeling and advertising.

Responding to Public Unsolicited Requests for off-label information, including emerging electronic media by drug or medical device firms

The Internet has revolutionized communication, information –sharing, information exchange among systems, and collaboration, enabling consumers to become more proactive about their health and safety. And as a result, the Internet has become widely used medium for manufactures and distributors to disseminate information about their products.
In some cases, this online content may not be accurate. Because the consumers increasingly use the internet to search for information about medical conditions and treatments, firms may receive public requests for off-label information about their products through, product websites, discussion boards, chat rooms or other electronic forums that they maintain and control.

The product information posted on websites & other public electronic forums that is likely to be available to a broad audience and for an indefinite period of time, FDA is concerned that firms may post public online responses to questions about off-label uses of their products in such a way that they are communicating unapproved use information about medical products to individuals who have not requested such information.

In such circumstances, communications to persons who have not requested information may promote a product a product for use or condition for which the FDA has not approved. FDA is also concerned about the enduring nature of the detailed public online responses to off-label questions because specific drug or device information may be outdated.

FDA makes the following recommendations to a firm that chooses to respond to public unsolicited request for off-label information about its products, including those encountered through emerging electronic media.

1. If a firm chooses to respond to public unsolicited requests for off-label information, the firm should respond only when the request pertains specifically to its own named product.

   The level of specificity of the question posed in a public forum is important in determining the appropriateness of a firm responding to the unsolicited request.

   Example: An individual poses the specific question "Can Drug/Device X be used for condition Y" in a public form. It may be appropriate for the firm to respond as outlined below because the question is unsolicited and specific to the firms named drug or device.

2. A Firm's public response to public unsolicited requests for off-label information about its named product should be limited to providing the firm's contact information and should not include any off-label information.

   The firm's public response should convey that the question pertains to an unapproved product use and the state that individuals can contact the medical/scientific representative or medical affairs department with the specific unsolicited request to obtain more information.

   The firm's public response should provide specific contact information for the medical personal or department (email, address, telephone) so that individuals can follow up independently with the firm to obtain specific information about the off-label use of the product through a non-public, one-on-one communication. After an individual has privately contacted a firm for more information regarding an off-label use of the firm's product, the firm should provide a detailed response and maintain records.

3. Representatives who provide public responses to unsolicited requests for off-label information should clearly disclose their involvement with a particular firm.

   FDA recommends that a representative who responds to a public request clearly disclose in his/her public response that he/she is a particular firm's representative and inform the requestor of the name of the firm representative or department to contact should the individual hose to follow up directly with the firm in a non-public for detailed information about the unsolicited request for off-label information.

4. Public responses to public unsolicited requests for off-label information described in numbers should not be overtly promotional in nature or tone.

   In addition to a firm's contact and disclosure information, a public response should include a mechanism for providing readily accessible current FDA-required labeling (package inserts, client information sheet). For example, a public online response should include a direct link to the current FDA-required labeling, if any, but should not include links to any other information (product websites, product promotional materials, firm websites, or third-party websites).